

burden of the proposed collection of information is as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
354(a)(3)(C)	20,000	1	1 (initial only)	.25	5,000

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimate for this proposed burden was derived from agency records and past experience concerning animal feed distribution.

Dated: December 3, 1997.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 97M-0499]

#### **ALLERGAN Medical Optics; Premarket Approval of Model SA40N AMO®ARRAY® Multifocal Ultraviolet-Absorbing Silicone Posterior Chamber Intraocular Lens**

**AGENCY:** Food and Drug Administration, HHS

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing its approval of the application by Allergan Medical Optics, Irvine, CA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Model SA40N AMO®Array® Multifocal Ultraviolet-Absorbing Silicone Posterior Chamber Intraocular Lens. After reviewing the recommendation of the Ophthalmic Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of September 5, 1997, of the approval of the application.

**DATES:** Petitions for administrative review by January 8, 1998.

**ADDRESSES:** Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

#### **FOR FURTHER INFORMATION CONTACT:**

Ashley A. Boulware, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2053.

**SUPPLEMENTARY INFORMATION:** On September 3, 1996, Allergan Medical Optics, Irvine, CA 92612-9534, submitted to CDRH an application for premarket approval of Model SA40N AMO®Array® Multifocal Ultraviolet-Absorbing Silicone Posterior Chamber Intraocular Lens. The device is a multifocal intraocular lens and is indicated for the visual correction of aphakia in persons 60 years of age or older in whom a cataractous lens has been removed and who may benefit from useful near vision without reading add and increased spectacle independence across a range of distances where the potential visual effects associated with multifocality are acceptable. The lens is intended for placement in the capsular bag. The lens is available in powers of +16 to +24 diopters.

On July 10, 1997, the Ophthalmic Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On September 5, 1997, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

#### **Opportunity for Administrative Review**

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request

either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before January 8, 1998, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: October 31, 1997.

**Joseph A. Levitt,**

*Deputy Director for Regulations Policy, Center for Devices and Radiological Health*

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